

## MEDICAL IMAGING, DIAGNOSIS, AND THERAPY USING A SCANNING SINGLE OPTICAL FIBER SYSTEM

### RELATED APPLICATIONS

[0001] This application is based on prior copending provisional patent application Ser. No. 60/212,411, filed on Jun. 19, 2000, the benefit of the filing date of which is hereby claimed under 35 U.S.C. § 119(e).

### FIELD OF THE INVENTION

[0002] The present invention generally relates to an optical fiber system that conveys light to and from a region of interest (ROI) on or within a living body, and more specifically, to a system that is selectively used for both imaging the ROI to facilitate a diagnosis, and for delivering therapy to the ROI.

### BACKGROUND OF THE INVENTION

[0003] The burgeoning field of minimally invasive medical procedures (MIMPs) has increased the demand for systems that produce less tissue damage and trauma, faster recovery times, and lower risks to the patient. Ideally, the practitioner of MIMPs requires smaller instruments that perform a greater variety of functions. Furthermore, a "one-instrument-does-all" approach must add simplicity, not complexity, by ensuring that it is easy to use, minimizing the time required to master its operation.

[0004] The instruments used by practitioners of MIMPs typically include several different discrete systems for optical imaging, monitoring, maneuvering, sizing, diagnosis, biopsy, therapy, surgery, and non-visual monitoring/sensing. It would be preferable to combine the functions provided by these instruments in a single compact device to reduce the number of surgical ports that are currently required for a plurality of single-function tools. By employing an integrated multi-functional tool so that only one small port is used, the risks associated with repeatedly removing and inserting surgical tools can be dramatically reduced. Since most MIMPs require the practitioner to constantly monitor the procedure visually, optical imaging is considered a requirement for any fully integrated system for MIMPs. Thus, an appropriate multifunction instrument will most likely include an optical imaging system, and the imaging system should be integrated with one or more diagnostic, and/or therapeutic tools.

[0005] The current tools used for MIMPs cannot readily be integrated without increasing the size of the resultant instrument to an excessive degree. All commercial optical imaging systems that include a maneuverable flexible shaft must maintain a certain size (diameter) in order to preserve image quality. Currently, flexible scopes cannot be made smaller than this limit unless image field of view (FOV) or resolution is sacrificed. Although imaging and some diagnostic capability can be integrated into existing scopes, such as standard tissue imaging in combination with fluorescence for early detection of cancers, the optical systems of current flexible scopes cannot provide integrated diagnoses and therapies at the required degrees of performance, size, and price that will be demanded in the future by medical practitioners.

### [0006] Current Technology Used for MIMPs

[0007] Presently available flexible scope designs use either a bundle of optical fibers (optical waveguides) and/or one or more cameras having an array of detectors to capture an image. Thus, the diameter of these flexible scopes employed for remote imaging cannot be reduced to smaller than the image size. Ignoring the optical fibers used for illumination, the scope diameter is therefore limited by the individual pixel size of a camera or by the diameter of optical fibers used to acquire the image. Currently, the smallest pixel element is determined by the size of the end of an optical fiber, which has a minimum core diameter of about 4  $\mu\text{m}$ . To propagate light through an optical fiber, a surrounding cladding layer is required, increasing the minimum pixel size to more than 5  $\mu\text{m}$  in diameter. If a standard VGA image is desired (e.g., with a resolution of 640×480 pixels), then a minimum diameter required for just the image optical fiber is more than 3 mm. Therefore, resolution and/or FOV must be sacrificed by having fewer pixel elements in order to achieve scopes with less than 3 mm overall diameter. All commercially available scopes suffer from this fundamental tradeoff between high image quality and small size.

[0008] Thus, it would be desirable to add diagnostic and therapeutic or surgical capability to a remote imaging system for the purpose of reducing the overall size of the instrument used for MIMPs. Since, for the reasons noted above, the current design for flexible scopes cannot readily be reduced in size without reducing imaging performance, the options for integrating diagnostic and therapeutic applications with an imaging system would appear to require an increase in the size of the instrument or use of separate instruments for each function. For example, a high intensity light source might be added to a general endoscopic surgical system to carry out photodynamic therapy (PDT) or laser surgery, or a polarized light source or other special light source might be needed for diagnosis and/or sensing a condition of an ROI. However, the white light illumination for standard endoscopic imaging is typically provided through an optical fiber bundle that diffusely illuminates the tissue and is incapable of providing a directed optical energy at high intensity and resolution to produce effective optical therapies, and will often not have the characteristics required for diagnostic processes. Therefore, any optical therapies that require directed illumination of high intensity light, such as PDT and laser surgery, or any diagnostic processes that also require a special light source cannot use existing optical designs for flexible imaging scopes, but instead, must rely on a second optical pathway and separate control mechanisms.

[0009] To perform diagnostic or therapeutic MIMPs, one or more separate instruments are used within the FOV of a standard endoscopic imager, and any additional separate instrument often must be held and maneuvered by a second medical practitioner. Typically, the second instrument provides a high intensity point source of light for optical therapies, a hot-tipped probe for thermal therapies, or a trocar used for mechanical cutting. The second instrument is moved to the surface of the tissue and usually moved within or across the surface of the tissue, covering the area of interest as the tool is scanned and manipulated by hand. These secondary instruments are inserted into the patient's body through a separate port, and thus, while being used, are